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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,327	04/27/2000	Mathew John During	40174	1919

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	15

DATE MAILED: 04/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application N .	Applicant(s)	
	09/559,327	DURING, MATHEW JOHN	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,10-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 8, 10-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *14 February 2003* is: a)☐ approved b)☒ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Non-Final Rejection

Claims 1-6, 8, and 10-12 are pending.

Drawings

New corrected drawings are required in this application because of the objection to the drawings by the draftsperson. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: the status (e.g., pending, abandoned, patented US Patent No.) of a US application listed on page 1, line 15 and 20 is missing.

Appropriate correction is required.

Claim Objections

Claim 8 is objected to because of the following informalities:

The wording of claim 8 is grammatically incorrect. Suggest inserting -- either – before the term "comprises" on line 1. Suggest inserting the word -- comprises -- before the term "non-AAV DNA" on line 3.

Claim Rejections - 35 USC § 112

Applicant's arguments, see paper no. 14, filed on 2/14/03, with respect to 112 enablement rejection have been fully considered and are persuasive. The rejection of claims 1-6, 8, and 10-12 has been withdrawn because of the amendment to the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "said non-AAV gene of interest comprises a β-galactosidase gene operatively linked to a promoter" in claim 12 is a relative term, which renders the claim indefinite. The term "said non-AAV gene of interest comprises a β-galactosidase gene operatively linked to a promoter" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The disclosure does not define the metes and bounds of the term because it is not apparent if there are one or two promoters being claimed. The specification does not define using two promoters in the AAV vector. Claim 12 depends on

claim 1. Claim 1 recites, "a non-AAV gene of interest operatively linked to a promoter operable in the gut". Thus, the term in claim 12 makes it unclear if another promoter is being used in the AAV vector.

Applicant's arguments with respect to claim 12 have been considered but are moot in view of the new ground of rejection under 112 second paragraph.

To overcome the 112 second paragraph rejection, suggest replacing the term "a promoter" with -- the promoter --.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 6, 8, and 10-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 7, 10, 16, 17, 18, 31, and 36 of U.S. Patent No. 6,503,887. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Patent No. '887

are drawn to a method for delivering a protein to a gut tissue of a subject comprising orally delivering to the gut tissue an AAV vector.

Although the conflicting claims in the instant application and the claims in '887 are not identical, they are not patentably distinct from each other because each invention encompasses the same material and methods and the claims in "887 embrace a method of orally delivering a recombinant AAV vector to the gut of a subject. The difference between the claims of the instant application and '887 is that the claims in the instant application are not as descriptive as the claims from the '887. Therefore, the claims of the instant application and '887 are obvious variants of one another.

Applicant's arguments with respect to claims 1, 10, and 11 have been considered but are moot in view of the new ground(s) of rejection. In addition, Applicant's arguments with respect to claims 5, 6, and 8 have been considered but are moot in view of the new ground(s) of rejection.

Claims 1, 2, 3, and 4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 7, 10, 16, 17, 18, 31, and 36 of U.S. Patent No. 6,503,887 in view of Sorscher et al. US Patent No. 5,552,311. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Patent No. '887 are drawn to a method for delivering a protein to a gut tissue of a subject comprising orally delivering to the gut tissue an AAV vector.

The difference between the claims of the instant application and the claims in '877 is that the instant application embraces using a liquid pharmaceutically acceptable carrier or a solid

pharmaceutically carrier. However, Sorscher teaches that depending on the mode of administration of a gene, one skilled in the art can use a solid composition or a liquid carrier (column 8, lines 10-58). Thus, one of ordinary skill in the art would have motivated to combine the methods claimed in U.S. Patent '887 in view Sorscher to use either a liquid pharmaceutically acceptable carrier or a solid pharmaceutical composition for delivering a recombinant AAV vector comprising a gene of interest operably linked to a promoter to the gut of a subject. One of ordinary skill in the art would have been motivated to use either pharmaceutical carrier because Sorscher teaches that the carriers are well known in the art for delivering a gene to a subject. Therefore, the claims of the instant application and patent '877 in view of Sorscher are obvious variants of one another.

Applicant's arguments with respect to claims 1, 2, 3, and 4 have been considered but are moot in view of the new ground(s) of rejection.

Claims 1 and 12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 7, 10, 16, 17, 18, 31, and 36 of U.S. Patent No. 6,503,887 in view of Horvath et al. (Hung. Ther. Vol. 37, pages 107-110, 1989). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Patent No. '887 are drawn to a method for delivering a protein to a gut tissue of a subject comprising orally delivering to the gut tissue an AAV vector.

The difference between the claims of the instant application and the claims in '877 is that the instant application embraces delivering a recombinant AAV comprising a non-AAV gene of interest comprises a β-galactosidase gene operatively linked to a promoter to a subject.

However, Horvath teaches administering β-galactosidase to patients with lactose malabsorption (pages 107 and 110). Thus, one of ordinary skill in the art would have motivated to combine the teaching in the claims of U.S. Patent '887 taken with Horvath to deliver an AAV vector comprising a β-galactosidase gene operably linked to a promoter to the gut of a subject with lactose malabsorption. One of ordinary skill in the art would have been motivated to delivery an AAV vector comprising a β-galactosidase gene operably linked to a promoter to the gut of a subject with lactose malabsorption because Horvath teaches that β-galactosidase can be used to treat lactose malabsorption. Therefore, the claims of the instant application and patent '877 in view of Horvath are obvious variants of one another.

Applicant's arguments with respect to claims 1 and 12 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe

Brian Whiteman
Patent Examiner, Group 1635

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER